



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

October 24, 2005

**FILE COPY**

Dr. Najib Babul  
Cinergen  
146 Medinah Drive  
Blue Bell, Pennsylvania 19422-3212

Dear Mr. Babul:

Your petition requesting the Food and Drug Administration to re-evaluate the prescribing info/package insert for new tramadol formulations in light of currently available safety information and designate extended release formulations of tramadol as Schedule III drugs under the Controlled Substances Act of 1970, as amended was received by our office on 10/24/2005. It was assigned docket number 2005P-0429/CP 1 and it was filed on 10/24/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2005P-0429

ACK1